BEFORE THE DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES OF THE STATE OF MONTANA

In the matter of the amendment of ARM)	NOTICE OF PROPOSED
37.12.401 pertaining to laboratory)	AMENDMENT
testing fees)	
-)	NO PUBLIC HEARING
)	CONTEMPLATED

TO: All Interested Persons

1. On June 17, 2006, the Department of Public Health and Human Services proposes to amend the above-stated rule.

The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who need an alternative accessible format of this notice. If you need to request an accommodation, contact the department no later than 5:00 p.m. on June 6, 2006, to advise us of the nature of the accommodation that you need. Please contact Dawn Sliva, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena, MT 59604-4210; telephone (406)444-5622; FAX (406)444-1970; e-mail dphhslegal@mt.gov.

2. The rule as proposed to be amended provides as follows. Matter to be added is underlined. Matter to be deleted is interlined.

37.12.401 LABORATORY FEES FOR ANALYSES (1) Fees for clinical and environmental analyses performed by the laboratory of the dDepartment of pPublic hHealth and hHuman sServices are set to reflect the actual costs of the tests and services provided. as follows, with the exception noted in (3):

(a) Microbiology Tests	Fee
(i) Anaerobic Culture	\$ 30.83
(ii) Autoclave Monitor	16.22
(iii) Bacterial Culture	28.66
(iv) Bacterial Screen	23.80
(v) C Diff Toxin	21.20
(vi) Chemclave Monitor	16.22
(vii) Chlamydia Amplification	18.93
(viii) EHEC Toxin	21.20
(ix) Enteric Panel	28.66
(x) Gonorrhea Amplification	18.93
(xí) Pertussis DFA	19.03
(xii) Legionella DFA	19.03
(b) Miscellaneous Test	
(i) Test sent out	8.11
(ii) Dangerous goods	54.08

(c) Mycology Tests	
(i) Fungal Culture, Skin	30.46
(ii) Fungal Culture, Other	30.46
(iii) Fungal Culture, Blood	30.46
(d) Newborn Tests	00.40
(i) IRT (Cystic Fibrosis)	9.88
(ii) Galactose	11.10
(iii) PKU	10.19
(iv) Hemoglobinopathy	8.17
(v) Thyroxine	9.88
(vi) TSH	8.71
(e) Parasitology Tests	0.71
(i) Crypto/Cyclo stain	22.93
(ii) O & P Conc. ID	
(iii) O & P, Trichrome	10.49
(f) Serology Tests	10.10
(i) Blood Lead	16.22
(ii) Brucella	14.87
(iii) CMV, IgG	
(iv) CMV, IgM	29.53
(v) Colorado Tick Fever	
(v) FTA	26.72
(vii) Hantavirus IgG	
(viii) Hantavirus IgM	
(ix) Hepatitis A IgM	\$ 25.00
(x) Hepatitis B core IgM	Ψ 25.00 25.00
(x) Hepatitis B Antibody	20.00
	19.25
` ' '	19.25 28.66
(xii) Hepatitis B core total	28.66
(xiii) Hepatitis B core total (xiii) Hep B Surface Antigen	28.66 17.09
(xii) Hepatitis B core total (xiii) Hep B Surface Antigen (xiv) Hepatitis C	28.66 17.09 28.66
(xii) Hepatitis B core total (xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2	28.66 17.09 28.66 32.88
(xiii) Hepatitis B core total (xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen	28.66 17.09 28.66 32.88 13.84
(xiii) Hepatitis B core total (xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen (xvii) HIV Western Blot	28.66 17.09 28.66 32.88 13.84 96.00
(xiii) Hepatitis B core total (xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen (xvii) HIV Western Blot (xviii) Legionella	28.66 17.09 28.66 32.88 13.84 96.00 16.44
(xiii) Hepatitis B core total (xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen (xvii) HIV Western Blot (xviii) Legionella (xix) Mumps	28.66 17.09 28.66 32.88 13.84 96.00 16.44
(xiii) Hepatitis B core total (xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen (xvii) HIV Western Blot (xviii) Legionella (xix) Mumps (xx) Q Fever	28.66 17.09 28.66 32.88 13.84 96.00 16.44 16.44
(xiii) Hepatitis B core total (xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen (xvii) HIV Western Blot (xviii) Legionella (xix) Mumps (xx) Q Fever (xxi) RMSF	28.66 17.09 28.66 32.88 13.84 96.00 16.44 16.44 16.44
(xiii) Hepatitis B core total (xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen (xvii) HIV Western Blot (xviii) Legionella (xix) Mumps (xx) Q Fever (xxi) RMSF (xxii) Rubella	28.66 17.09 28.66 32.88 13.84 96.00 16.44 16.44 16.44
(xiii) Hepatitis B core total (xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen (xvii) HIV Western Blot (xviii) Legionella (xix) Mumps (xx) Q Fever (xxi) RMSF (xxiii) Rubella (xxiiii) Rubeola	28.66 17.09 28.66 32.88 13.84 96.00 16.44 16.44 16.44 16.44
(xiii) Hepatitis B core total (xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen (xvii) HIV Western Blot (xviii) Legionella (xix) Mumps (xx) Q Fever (xxi) RMSF (xxii) Rubella (xxiii) Rubeola (xxiv) Tularemia	28.66 17.09 28.66 32.88 13.84 96.00 16.44 16.44 16.44 16.44 16.44 16.44
(xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen (xvii) HIV Western Blot (xviii) Legionella (xix) Mumps (xx) Q Fever (xxi) RMSF (xxii) Rubella (xxiii) Rubeola (xxiv) Tularemia (xxv) Toxo IgG	28.66 17.09 28.66 32.88 13.84 96.00 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44
(xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen (xvii) HIV Western Blot (xviii) Legionella (xix) Mumps (xx) Q Fever (xxi) RMSF (xxii) Rubella (xxiii) Rubeola (xxiv) Tularemia (xxv) Toxo IgG (xxvi) Toxo IgM	28.66 17.09 28.66 32.88 13.84 96.00 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 29.53
(xiii) Hepatitis B core total (xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen (xvii) HIV Western Blot (xviii) Legionella (xix) Mumps (xx) Q Fever (xxi) RMSF (xxii) Rubella (xxiii) Rubeola (xxiv) Tularemia (xxv) Toxo IgG (xxvii) Varicella Zoster	28.66 17.09 28.66 32.88 13.84 96.00 16.44 16.44 16.44 16.44 16.44 16.44 16.44 29.53
(xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen (xvii) HIV Western Blot (xviii) Legionella (xix) Mumps (xx) Q Fever (xxi) RMSF (xxii) Rubella (xxiii) Rubeola (xxiv) Tularemia (xxv) Toxo IgG (xxvii) Varicella Zoster (xxviii) VDRL, qua	28.66 17.09 28.66 32.88 13.84 96.00 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44
(xiii) Hepatitis B core total (xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen (xvii) HIV Western Blot (xviii) Legionella (xix) Mumps (xx) Q Fever (xxi) RMSF (xxii) Rubella (xxiii) Rubeola (xxiv) Tularemia (xxv) Toxo IgG (xxvi) Toxo IgM (xxvii) Varicella Zoster (xxviii) VDRL, qua (xxix) West Nile Virus	28.66 17.09 28.66 32.88 13.84 96.00 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 10.83 15.00
(xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen (xvii) HIV Western Blot (xviii) Legionella (xix) Mumps (xx) Q Fever (xxi) RMSF (xxii) Rubella (xxiii) Rubeola (xxiv) Tularemia (xxv) Toxo IgG (xxvi) Toxo IgM (xxviii) Varicella Zoster (xxiii) VDRL, qua (xxix) West Nile Virus (xxx) VDRL, quant	28.66 17.09 28.66 32.88 13.84 96.00 16.44 16.44 16.44 16.44 16.44 16.44 29.53 16.44 29.53 16.44 10.83 15.00 10.98
(xiii) Hepatitis B core total (xiii) Hep B Surface Antigen (xiv) Hepatitis C (xv) Herpes simplex 1 & 2 (xvi) HIV screen (xvii) HIV Western Blot (xviii) Legionella (xix) Mumps (xx) Q Fever (xxi) RMSF (xxii) Rubella (xxiii) Rubeola (xxiv) Tularemia (xxv) Toxo IgG (xxvi) Toxo IgM (xxvii) Varicella Zoster (xxviii) VDRL, qua (xxix) West Nile Virus	28.66 17.09 28.66 32.88 13.84 96.00 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 16.44 10.83 15.00

(i) Acid Fast Stain	11.46
(ii) Mycobact. Culture	17.01
(iii) Mycobact. Concentration	9.59
(iv) Mycobact. Suscept., each drug	12.00
(v) Mycobact. Sp. Probe	19.03
(vi) Mycobact. Avium Probe	19.03
(vií) Mycobact. TB Probe	19.03
(viii) Mycobact. TB AMP	145.60
(h) Virology Tests	
(i) Chlamydia Culture	30.50
(ii) Herpes Culture	20.00
(iii) Direct Detection (RSV, VZV, HSV)	19.03
(iv) Virus ID (IFA)	9.52
(v) Viral Culture	30.50
(vi) Virus ID (neutralize)	40.00
(i) Molecular Testing	
(i) PCR, 1 agent	60.00
(ii) PFGE, 1 enzyme	66.25
(iii) Hep C, PCR	101.92
(2) Effective December 1, 2003, fees for environmental ar	•
by the laboratory of the department of public health and human so	ervices are as
follows, with the exceptions noted in (3) and (4):	
(a) Fees for nutrient analyses are as follows:	0.4450
(i) Nitrate plus nitrate as N	\$ 14.50
(ii) Nitrite	14.50 14.50
(iii) Ortho phosphorus (iv) Soluble phosphorus	
(v) Total ammonia as N	
(vi) Total phosphorus	
(vii) Total kjeldahl nitrogen	24.73 28.75
(b) Fees for metal analysis by ICP are as follows:	20.73
(i) Aluminum	9.20
(ii) Antimony	17.25
(iii) Arsenic	17.25
(iii) Attacine	
(v) Beryllium	
(vi) Bismuth	
(vii) Boron	
(viii) Calcium	
(ix) Cadmium	
(x) Cobalt	9.20
(xi) Copper	
(xii) Chromium	
(xiii) Dust wipes	
(xiv) Iron	
(xv) Lead	
(xvi) Lithium	

(xvii) Magnesium	9.20
(xviii) Manganese	9.20
(xix) Metals scan, water, 17 element	
(xx) Metals scan, water, 25 element	
(xxi) Metals scan, solids, 20 element	
(xxii) Molybdenum	
(xxiii) Nickel	
(xxiv) Potassium	
(xxv) Silicon	
(xxvi) Silver	
(xxvii) Sodium	
(xxviii) Strontium	
(xxix) Tin	
(xxx) Titanium	
(xxxi) Vanadium	
(xxxii) Zinc	
(xxxiii) Selenium	
(xxxiii) Colonium (xxxiv) Thallium	17.25 17.25
(c) Fees for organic analyses are as follows:	17.20
(i) Organic analyses in drinking water:	
(A) 505 - Organohalide pesticides	\$ 172 50
(B) 508 - Chlorinated pesticides	
(C) 515 - Chlorophenoxy herbicides	
(D) 525 - Synthetic organic compounds	
(E) 531 - Carbamate pesticides	
(F) Haloacetic acids	
(G) Trihalomethanes	
(H) VOC - volatile organic compounds	
(ii) For organic analyses in other substrates, EPA 600 a	
fees are:	na oooo senes, the
(A) Organohalide pesticides	230.00
(B) Chlorinated pesticides	230.00
(C) Chlorophenoxy herbicides	265.00 265.00
(D) Synthetic organic compounds	276.00
(E) Carbamate pesticides	230.00
(F) Haloacetic acids	207.00 207.00
(G) Trihalomethanes	
(H) VOC - volatile organic compounds	276.00
(d) Fees for fuel analyses are as follows:	270.00
(i) Blue dye in fuel	8.63
•	8.63
(ii) Red dye in fuel (iii) Dyed fuel combo	0.03
(excludes blue dye in fuel)	55.00
(iv) Diesel characterization	34.50
(v) Sulfur by XRF	23.00
(e) Fees for commons are as follows:	15.00
(i) Alkalinity (ii) Chloride	15.00 20.00
(III) Official	20.00

	0.00
(iii) Conductivity	6.90
(iv) Fluoride	<u>17.25</u>
(v) pH	6.90
(vi) Sulfate	20.00
(vii) TDS	9.20
(viii) TSS	9.20
(ix) Volatile suspended solids	25.76
(f) Fees for air quality analyses are as follows:	
(i) Dustfall	34.50
(ii) Fiberglass hi vol filters	7.00
(iii) PM 10	7.00
(iv) PM 2.5	17.25
(v) PM 2.5p	23.00
(vi) Lead analysis on filters	19.55
(g) Fees for miscellaneous tests are as follows:	
(i) Acidity	14.50
(ii) BOD	\$ 40.25
(iii) Chlorophyll	31.75
(iv) CBOD	40.25
(v) COD	40.25
(v) Color	23.00
(vii) Cyanide - drinking water	40.25
(viii) Hardness	20.70
(ix) Hexavalent chromium	28.75
(x) Mercury	41.40
	14.50
(xi) Mercury composited	
(xii) Oil and grease	51.75
(xiii) Phenol	28.75
(XIV) Calliac	40.25
(xv) TOC	29.90
(xvi) Turbidity	6.90
(h) Fees for microbiology testing are as follows:	
(i) Total coliform	
(ii) Fecal coliform - membrane filtration	
(iii) Iron bacteria	19.00
(iv) Sulfur bacteria	
(v) Heterotrophic plate count	19.00
(i) Fees for special handling are as follows:	
(i) Rush fee - per sample order	10.00
(ii) Microwave digestion	19.55
(iii) Nutrient extraction	15.00
(iv) Total metals digestion	17.25
(v) Total recoverable metals digestion	11.50
(vi) VOC extraction - TCLP	
(vii) Metals extraction - TCLP	51.75
(2) The Department of Public Health and Human Services shall	

(2) The Department of Public Health and Human Services shall maintain a list of all tests available from the lab and the price of each test. The department

adopts and incorporates by reference the Laboratory Test Fee List effective July 1, 2006, which shall be available on the website of the Department of Public Health and Human Services at www.dphhs.mt.gov, and by mail upon request to the lab at the Department of Public Health and Human Services, Public Health and Safety Division, P.O. Box 6489, Helena, MT 59604-6489.

- (3) The fees specified in (1) and (2) for a specific lab test will be lowered by the dDepartment of pPublic hHealth and hHuman sServices to a level not exceeding the cost to the department of the test in question whenever a change of analysis method warrants lower fees.
- (4) Fees for analyses other than those listed in (1) and (2) will be established at the level of comparable analyses.

AUTH: <u>50-1-202</u>, MCA IMP: <u>50-1-202</u>, MCA

3. Title 37, Chapter 12, rule 401 of the Administrative Rules of Montana (ARM) provides information regarding the fees charged for biological and environmental tests performed by the Montana state laboratory, in conformity with state statute. The Department of Public Health and Human Services (the department) proposes the following modifications to existing rules to bring the fees charged for lab services in line with the actual current costs associated with providing those services. As well, the department proposes to modify the forum of distribution of the lab service and fee list to ensure timely notification of additions to lab services, and to provide greater accessibility to the most current list of services and fees by all Montana citizens wanting to utilize the services to the state laboratory.

The proposed fee increases will result in a cumulative increase in fees for all laboratory services of approximately \$182,000, affecting the approximately 1,000 annual customers of the state laboratory. The fee increases proposed represent the minimum increases in fees required to maintain the state laboratory's current level of services, and are reasonably necessary to allow the state laboratory to fulfill its obligations as an adjunct to public health and health care functions in the state of Montana.

The department has modified ARM 37.12.401(1) and (2) to clarify that the testing services provided by the state laboratory include both clinical (biological) testing and environmental testing services. These modifications do not indicate a change in functioning by the laboratory, but merely clarify for citizens looking for laboratory services what services may be obtained from the state laboratory.

In addition, these sections have been modified to identify the pricing methodology applicable to state laboratory services and to remove the specific list of laboratory tests and associated fees from this rule in favor of distribution via the internet and by mail. The department believes that making the service and fee list available via the internet, with the list also being available by mail upon request, will ensure that all Montana citizens will have timely access to a complete, accurate list of testing services and their associated fees. As well, the department believes that

the information is more readily available to more people and at a far lower cost if it is available via the internet and mail than if it is available only in the ARM or by phone call to the laboratory.

The department considered continuing the practice of including the service and fee list in the ARM, but concluded that such continued practice would result in less accurate information being available to consumers of state laboratory services as the list could only be updated to include new services pursuant to a rule modification.

Finally, the fees applicable to all testing services have been increased to account for the increased costs incurred by the laboratory over the past several years, including increased personnel costs, increased costs of supplies, and increased costs of new and replacement testing equipment.

The department considered not increasing its testing fees, but concluded that doing so would result in the laboratory spending more to provide services than it would recover in service fees, and eventually would render the laboratory unable to provide any level of service.

ARM 37.12.401(3) and (4) have been modified to reflect the removal of the service/fee list from the ARM.

Other Modifications

Other minor modifications may have been made within these rules to conform the rules to the requirements of the Secretary of State regarding rule drafting, including but not limited to, formatting, numbering, capitalization, hyphenation, and internal reference to other provisions/rules. These modifications are not substantive and do not modify the meaning or intent of the rules.

- 4. Interested persons may submit their data, views, or arguments concerning the proposed action in writing to Gwen Knight, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 202951, Helena, MT 59620-2951, no later than 5:00 p.m. on June 15, 2006. Data, views, or arguments may also be submitted by facsimile (406)444-9744 or by electronic mail via the Internet to dphhslegal@mt.gov. The department also maintains lists of persons interested in receiving notice of administrative rule changes. These lists are compiled according to subjects or programs of interest. For placement on the mailing list, please write the person at the address above.
- 5. If a person who is directly affected by the proposed action wishes to express data, views, and arguments orally or in writing at a public hearing, that person must make a written request for a public hearing and submit such request, along with any written comments to Gwen Knight, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 202951, Helena, MT 59620-2951, by facsimile (406)444-9744 or by electronic mail via the Internet to

dphhslegal@mt.gov no later than 5:00 p.m. on June 15, 2006.

6. If the Department of Public Health and Human Services receives requests for a public hearing on the proposed action from either 10% or 25, whichever is less, of those who are directly affected by the proposed action, from the administrative rule review committee of the legislature, from a governmental agency or subdivision, or from an association having no less than 25 members who are directly affected, a hearing will be held at a later date and a notice of the hearing will be published in the Montana Administrative Register. Ten percent of those directly affected has been determined to be 95 based on the 950 customers affected by rules covering the state laboratory fees and services.

/s/ Russell E. Cater
Rule Reviewer

/s/ Russell E. Cater for
Director, Public Health and
Human Services

Certified to the Secretary of State May 8, 2006.